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SEP - 6 2011

Office of Regulatory Policy Food and Drug Administration 10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,599,498. The application was filed on July 24, 2009, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Senior Legal Advisor

Office of Patent Legal Administration Office of the Associate Commissioner

for Patent Examination Policy

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RE: FERAHEME® (ferumoxytol) Docket No. FDA-2010-E-0049